



## Medical Device Details

Sponsor: Ossur New Zealand Limited  
6/80 Westpoint Drive  
Hobsonville  
Auckland  
New Zealand

WAND Reference: 230124-WAND-70JK4Q

Sponsors Own Reference: OPC - Even up

GMDN: Orthotic shoe, ready-made [31041]

Class: I

Intended Purpose: footwear designed as a shoe intended to support, align, prevent, and compensate for or correct deformities of the feet

Manufacturer: OPC Health 151-159 Turner Street  
Port Melbourne  
Victoria  
Australia

ARTG ID:

- › The device is supplied unsterilised.
- › The device is not intended to be invasive.
- › The device is not intended for single use.
- › The device is not an active device.
- › The device does not contain material or ingredients of microbial origin.
- › The device does not contain material or ingredients of recombinant origin.
- › The device does not contain material or ingredients manufactured or formulated using a genetically modified organism.
- › The device does not contain material or ingredients of human origin.
- › The device does not contain human blood or its components.
- › The device consists of: Single product
- › The device does not contain material or ingredients of animal origin.
- › The device is not medicated.
- › The device is not formulated.
- › The product does not contain a medicine that has consent for marketing in New Zealand.
- › The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.

Status: Active